

Code: 1052-36177

JAPANESE PATENT OFFICE

PATENT JOURNAL

KOKAI PATENT APPLICATION NO. HEI 5[1993]-269159

Technical Disclosure Section

Int. Cl. ⁵ :	A 61 F 2/44 5/01
Sequence Nos. for Office Use:	7180-4C 7807-4C
Application No.:	Hei 5[1993]-28484
Application Date:	January 26, 1993
Publication Date:	October 19, 1993
Priority:	
No.:	07/827002
Date:	January 28, 1992, U.S.
Country:	U.S.
No. of Claims:	34 (Total of 6 pages)
Examination Request:	Not requested

SYNOSTOSIS DEVICE AND BONE ARCHITECTURE HEALING ACCELERATION
DEVICE

Inventor:	David F. Kluck 2145 Sodo Drive, Garland, Texas, U.S.A. 75044
-----------	---

[Names and addresses are transliterations.]

Applicant:

592239383
American Medical
Electronics Incorporated
250 East Arapaho Road,
Richardson, Texas, U.S.A.
75081

Agent:

Masazo Sanada, patent
attorney, and 1 other

[There are no amendments to this patent.]

Abstract

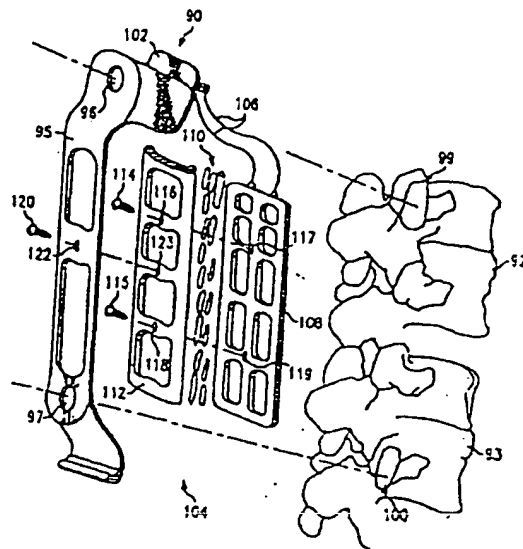
Objective

To execute the stimulation of bone growth and fusion by stabilizing the injured region or the fusion region and execute effective distribution of stimulation energy to the injured region.

Constitution

Bone graft piece (110) is positioned directly on conductive mesh frame (108) in contact with injured bone regions (99) and (100). Retainer (112) is fixed to said conductive mesh frame and a bone graft piece is interposed between said retainer. Brace (95) is fixed to the retainer, and the brace is fixed to the bone architecture directly above the injured region. The brace effectively pressurizes the retainer and closely contacts the fused bone and injured region. Furthermore, electronic module

(102) is attached to the brace, coupled to the conductive mesh frame, and stimulation energy is delivered to said conductive mesh frame.



Claims

1. A synostosis device which includes a cage attached directly to the injured bone region and essentially surrounds the bone graft piece in a synostosis device which executes bone fusion by holding a bone in the injured bone region.

2. A synostosis device of Claim 1 provided with a circuit which is fixed close to said injured bone region and generates stimulation energy,

and a conductive means which couples said circuit and said cage, and said cage receives said stimulation energy and is energized.

3. A synostosis device of Claim 1 which provides a conductive mesh frame to said cage,

and a retainer which is fixed to said conductive mesh frame and interposes said fused bone between said conductive mesh frame.

4. A synostosis device of Claim 1 provided with a brace which is coupled removably to said cage and is fixed removably to said injured bone region, and pressure is applied to said cage with said brace towards the injured bone region so that said cage and said injured bone region are in close contact.

5. A synostosis device of Claim 4 which couples said circuit means to said brace and is then stored within said brace.

6. A synostosis device of Claim 5 which forms a cavity suited for storing said circuit means with said brace.

7. A synostosis device of Claim 4 which sets the contour of said brace so that it corresponds exactly with the contour of the bone architecture surrounding said injured bone region at said injured bone region.

8. A synostosis device of Claim 4 which provides said brace with at least one part which contacts at least one point on the bone architecture surrounding said injured bone region, and sets the contour of said one part to correspond with the contact point of said bone architecture.

9. A synostosis device in Claim 1 in which said cage is flexible in essence.

10. A bone architecture healing acceleration device which includes a conductive mesh frame,

a bone graft which is directly positioned on said conductive mesh frame,

a retainer which is fixed to said conductive mesh frame and interposes said bone graft between it and said conductive mesh frame,

a brace which is fixed to said retainer, fixed to said bone architecture directly over the injured region, and stabilizes said bone architecture by effectively pressurizing said conductive mesh frame, said bone graft, and said retainer in said injured region,

and an electronic module which is attached to said brace, coupled to said conductive mesh frame, and stores the electronic circuit for feeding stimulation energy to said conductive mesh frame, in a bone architecture healing acceleration device which accelerates the healing of injured bone architecture.

11. A bone architecture healing acceleration device in Claim 10 in which, when the injury is between multiple vertebrae, said brace is fixed to said vertebrae and holds said conductive mesh frame and bone grafts directly to said injured region.

12. A bone architecture healing acceleration device of Claim 10 in which said conductive mesh frame is flexible in essence.

13. A bone architecture healing acceleration device of Claim 10 which sets the contour of said brace to correspond exactly with the contour of said bone architecture.

14. A bone architecture healing acceleration device of Claim 13 in which said brace is provided with at least one part which contacts at least one point on said bone architecture and the contour of said one part is set to correspond with the contact point of said bone architecture.

15. A bone architecture healing acceleration device of Claim 10 which fixes said retainer to said conductive mesh frame with a fastener.

16. A bone architecture healing acceleration device of Claim 10 which fixes said brace to said retainer with a fastener.

17. A bone architecture healing acceleration device of Claim 10 which fixes said brace to said bone architecture with a screw.

18. A bone architecture healing acceleration device of Claim 10 which provides a rod with a hook at each end of said brace and is made suitable for fixing said brace to the bone architecture by hooking said hook to the indicated constitutional part of said bone architecture.

19. A bone architecture healing acceleration device which includes a bone graft,

a conductive mesh housing which stores said bone graft,
a brace which is superimposed on said conductive mesh housing, fixed to it, fixed to said bone architecture directly on said injured region, effectively pressurizes said conductive mesh housing and bone graft to said injured part, and makes said bone architecture immovable,

and an electronic module which is attached to said brace, coupled to said conductive mesh housing, and delivers stimulation energy to said conductive mesh housing,

in a bone architecture healing acceleration device which accelerates the healing of injured bone architecture.

20. A bone architecture healing acceleration device of Claim 19 in which, when said injury is an unstable segment between multiple vertebrae, said brace is fixed to each of said

vertebrae and said conductive mesh housing and bone grafts are held directly to the region with said unstable segment.

21. A bone architecture healing acceleration device of Claim 19 in which said conductive mesh housing is flexible in essence.

22. A bone architecture healing acceleration device of Claim 19 which sets the contour of said brace to correspond exactly with the contour of said bone architecture.

23. A bone architecture healing acceleration device of Claim 22 which provides at least one part to said brace which contacts at least one point on said bone architecture and sets the contour of said one part to correspond with the contact point of said bone architecture.

24. A bone architecture healing acceleration device of Claim 19 which fixes said brace to said conductive mesh housing with a fastener.

25. A bone architecture healing acceleration device of Claim 19 which fixes said brace to said bone architecture with a screw.

26. A bone architecture healing acceleration device of Claim 19 which provides a rod with a hook to each end of said brace, and is made suitable for fixing said brace to said bone architecture by hooking said hook to the indicated constitutional part of said bone architecture.

27. A bone architecture healing acceleration device which includes a bone graft,

a conductive means with multiple holes for holding said bone graft,

a brace which fixes said conductive means and bone graft to said bone architecture directly onto said injured region and effectively makes said bone architecture immovable,

and an electronic circuit which is attached to said brace and delivers stimulation energy to said conductive means,

in a bone architecture healing acceleration device which accelerates the healing of injured bone architecture.

28. A bone architecture healing acceleration device of Claim 27 in which, when said injury is between multiple vertebrae, said brace is fixed to each vertebra and said conductive means and multiple bone grafts are held directly to said injured region.

29. A bone architecture healing acceleration device of Claim 27 in which said conductive means is flexible in essence.

30. A bone architecture healing acceleration device of Claim 27 which sets the contour of said brace to correspond exactly with the contour of said bone architecture.

31. A bone architecture healing acceleration device of Claim 30 which provides at least one part of said brace which contacts at least one point of said bone architecture and sets the contour of said one part to correspond with the contact point of said bone architecture.

32. A bone architecture healing acceleration device of Claim 27 which fixes said brace to said conductive means with a fastener.

33. A bone architecture healing acceleration device of Claim 27 which fixes said brace to said bone architecture with a screw.

34. A bone architecture healing acceleration device of Claim 27 which provides a rod having a hook at each end of said brace, hooked with each hook to the indicated constitutional part of said bone architecture, and said brace is fixed to said constitutional part.

Detailed explanation of the invention

[0001]

Industrial application field

Said invention relates generally to the field of medical equipment. Specifically, said invention relates to a device which provides distributed bone growth stimulation while maintaining local stability.

[0002]

Background of the invention

Miniaturization of electronic circuits accelerated the epochal progress in many areas of our daily lives. Noticeable examples range from laptop computers and pocket televisions to international positioning systems which provide sensory feedback to the user and artificial organs. Progress in electronic engineering has promoted research and development in the area of orthopedic bone growth stimulation including acceleration of spinal fusion and healing. This is executed by inserting a

current generator in the vicinity of the broken bone within the patient's body so that direct current flows at the periphery of said broken bone part. Research indicates that when stimulation is applied to a broken bone, speed in the growth and healing of the bone is improved. In other effective stimulation methods, ultrasonic waves delivered through the broken bone region are used.

[0003]

In addition to said bone growth stimulation, electronic equipment inserted into the body also aids in monitoring the health of the patient. For example, the process of bone growth is determined by the amount of electrical resistance of the bone. Also, ultrasonic imaging can be executed by inserting an ultrasonic transmitter and receiver at the mutually opposing regions which target the problematic area. A detailed explanation of this type of ultrasonic imaging system is noted in said affiliated patent specifications.

[0004]

However, the conventional method which inserts an electronic circuit has a disadvantage in which there is the possibility of movement in the electronic parts including the electronic circuit package, electrode, and storage battery pack, which causes short circuiting of the device's output. The broken and fused bone regions are mechanically unstable so producing internal stability is a normal medical practice. Therefore, a

device which carries out stimulation of bone growth and fused by stabilizing the broken bone or the fusion region is necessary. Also, a device which carries out distributed delivery of stimulation energy to the injured region is necessary.

[0005]

Summary of the invention

According to said invention, a device can be obtained which carries out fixation and stimulation of bones which essentially eliminate or reduce the disadvantages and problems accompanying the application of the conventional technology.

[0006]

In one mode of said invention, a device which carries out bone fusion by holding a bone graft to the injured region of the bone can be obtained. This device is provided with a cage attached directly to the broken bone region so as to surround the bone graft, in essence. In the vicinity of the broken bone region, a circuit which generates stimulation energy is attached. Stimulation energy is transmitted to the cage. The bone injury is created by external force or surgically.

[0007]

In another mode of said invention, a device which accelerates the healing of the injured bone architecture is

obtained. Multiple broken bone pieces are directly positioned on a conductive mesh frame held to the injured region of the bone. A retainer is fastened to said conductive mesh frame and the broken pieces of the bone are inserted between them. A brace is fastened to said retainer and this brace is fixed to the bone architecture directly over the injured region. The brace effectively applies pressure to the retainer and brings the fused bone and injured region into close contact. Furthermore, an electronic module is attached to the brace, coupled to the conductive mesh frame, and stimulation energy is delivered to said conductive mesh frame.

[0008]

As an important technological advantage of said invention, one device is obtained which essentially provides both stability to the injured region and stimulation for accelerating the healing. Furthermore, the bone growth is accelerated further by using a bone graft fixed directly to the injured region.

[0009]

Application examples

In the appended figures, Figure 1 is a development figure for the first application example of device (10) for bone fixation and stimulation composed according to said invention. Device (10) of said invention is provided with parts and optional parts. The structure of these parts are stored in the computer

aided design (CAD) library (not shown in the figure). Each part can be selected from the CAD library by the doctor or practitioner according to the predetermined, necessary items for the patient. For example, when the determination is made that electric field stimulation which combines reading the resistance and telemetry is preferable for optimal healing acceleration and monitoring with respect to a specific patient, device (10) is composed of parts selected from the library for manifesting said functions.

[0010]

Device (10) is provided with baseplate (12). Baseplate (12) is provided with fixation means (13) and (14) which securely couple the bone on the bottom side (not shown in the figure) and baseplate (12). Each fixation means (13) and (14) is positioned in the same plane as baseplate (12) or in an optional orientation, and is provided with a hole for receiving the fastener which fixes baseplate (12) to the bottom side of the bone. The hole in each fixation means (13) and (14) can be formed as one unit with the baseplate (12) or can be composed separately as shown in the figure, then attached to the baseplate (12). Also, device (10) can be composed by the stereolithographic method and all selected parts formed in one unit as a single product composed of an implantable source material such as titanium stainless steel, cobalt chromium steel, or a suitable plastic material, ceramic material, and carbon fiber composite product.

[0011]

Also, fixation means (13) and (14) are provided with means (15) (one example is shown in Figure 3) which receives a rod to fix device (10) to the bottom side of the bone architecture. This stabilization method is particularly suited for fixing injured spinal columns.

[0012]

To baseplate (12), electronic module housing (17) is formed which surrounds electronic module (20) along with cover plate (22). Ideally, the internal cavity of electronic module housing (17) closely follows the outer contour of electronic module (20) without leaving unused space in the outer contour of electronic module (20) in essence. Also, it is preferable for electronic module (20) to be provided with an insulated housing (24) to store the electronic circuits (not shown in the figure). When multiple electronic modules are necessary, for example, mutual connector (26) which connects additional electronic module (28) to electronic module (20) is used. Electronic module housing (17) and cover plate (22) can be enlarged to store the additional electronic module (28) and mutual connector (26). An additional part is provided, for example, an electrode (30) for delivering electrical energy to the bone architecture. Each electrode (30) can be connected to electronic module (20) with connector (32) which screws to electronic module housing (17).

[0013.]

Device (10) is shown as a development figure in Figure 1 so that the independent parts can be shown more favorably. However, if parts considered favorable for a specific use are selected, it is preferable to make the device into one unit. For example, compose all parts (excluding electronic modules (20) and (28), mutual connector (26) for the modules, and cover plate (22)) including the fastenings, namely fixation means (13), (14), or (15), baseplate (12), and electronic module housing (17) by forming or molding a single material. Furthermore, an interface plate (34) which can be formed as one unit with baseplate (12) is provided. Surface (35) of interface plate (34) is prepared by rastographic data collection, computer aided design, and stereolithographic modeling, and its surface contour is the reverse image of the bone surface to which device (10) is fixed. By so doing, a closely assembled surface is obtained in which device (10) does not displace or slip with respect to the bone architecture on the bottom side.

[0014]

In Figure 2, which shows one modification of said invention, a perspective view of a large H-shaped device (40) for bone fixation and stimulation is shown. The device (40) is provided with a large H-shaped brace structure (42) having cavities (44) and (46) for storing electronic modules (48)-(52) which carry out, for example, bone stimulation, fusion monitoring, telemetry, pain control, and other functions. Device (40) is made to

) include the electronic module functions considered necessary for the specific patient, as noted above. Furthermore, storage battery (54) is provided to supply the necessary power to electronic modules (48) and (52). Cavities (44) and (46) are closed with cover plates (56) and (58), forming the airtight sealed part in essence by fastening with fastener (60) or welding. Furthermore, hole (62) is provided to said cover plates (56) and (58) in order to pass through, for example, electrode lead (64). Device (40) is fastened to the injured region of the bone by inserting a fastener (not shown in the figure) such as a bolt, screw, etc., through each hole (6)-(69).

[0015]

Figure 3 shows another application of said invention. Device (70) utilizes the rod fixation method which uses rod (72) with hooks (74) and (75) at each end. Hooks (74) and (75) securely fix device (70) to the injured region or in its vicinity and it is hooked to the constitutional part of the vertebrae within the spinal column to stabilize the injured vertebrae or the intervertebral disk. Rod (72) is attached securely to baseplate (76) or attached to baseplate (76) by inserting rod (72) into saddle-shaped members (78) and (79), formed as one unit. It is preferable for baseplate (76) to have surface (82) which corresponds in essence to the constitutional part of the injured bone to which device (70) is fixed. As mentioned above, surface (82) is constituted with rastographic data collection, computer aided design, and stereolithographic modeling.

[0016]

A development figure for another application example of said invention is shown in Figure 4. As shown in the figure, device (90) is composed mainly to provide stimulation by carrying out fixation with respect to an injured region positioned between two vertebrae (92) and (93) of the spinal column. The injury, for example, may be a segmental instability in which it may be necessary for two vertebrae (92) and (93) on each side of the injured intervertebral disk to be mutually fixed during the time fusion is being carried out.

[0017]

Device (90) is provided with brace (95) having a shape and contour which exactly follow the attachment region of the spinal column. The contour forming is executed by said rastographic data collection, computer aided design, and stereolithographic modeling in order to obtain a brace which is produced according to order to fix the particular part of each patient. Brace (95) is made oblong, as shown in Figure 4, and has two end parts. Holes (96) and (97) are formed in both end parts and are made to receive the screws (not shown in the figure) for fastening device (90) to regions (99) and (100) on respective vertebrae (92) and (93). The other fastening means, like the rod structure shown in Figure 3, can also be applied in this application example.

[0018]

Electronic module (102) is attached to brace (95). Electronic module (102) manifests numerous functions, including said synostosis stimulation, telemetry, fusion monitoring, etc. However, in this application example, electric field distribution device (104) is provided to enhance the function of electric field stimulation. Electronic module (102) is simply coupled to brace (95) as shown in the figure or stored within the cavity of brace (95). A pair of electrode leads (106) extend from electronic module (102) and are coupled to mesh electrode frame (108). Mesh electrode frame (108) is usually composed of a flexible conductive material, in essence. Mesh electrode frame (108) accelerates the healing by providing a mesh frame which improves the distribution of the electromagnetic energy which surrounds the injured region.

[0019]

Bone or bone graft (110) and retainer (112) for the bone graft make contact at the apex of mesh electrode frame (108). Namely, fused bone (110) is interposed between mesh electrode frame (108) and retainer (112) and they are held together by fasteners (114) and (115). It is preferable for fasteners (114) and (115) to be inserted into retainer (112) and mesh electrode frame (108) through screw holes (116) and (117) and screw holes (118) and (119), respectively. Electric field distribution device (104) is coupled to brace (95) with a fastener such as

screw (120). Screw (120) is received respectively in screw holes (122) and (123) of brace (95) and retainer (112).

[0020]

During the operation, electronic module (102) delivers current to mesh electrode frame (108) by electrode lead (106). Each fused bone (110) stimulated by the current within mesh electrode frame (108) grows and bonds in the area between vertebrae (92) and (93) to a greater degree. When the fusion ends, retainer (112) of the fused bone and brace (95) are removed from this region along with electronic module (102).

[0021]

Said invention was explained in detail above but, needless to say, said invention can be variously modified in its scope without deviating from the spirit.

Brief explanation of the figures

Figure 1 is a development perspective view of a favorable application example of said invention.

Figure 2 is a perspective view showing another favorable application example of said invention by cutting out one part.

Figure 3 is a perspective view of yet another favorable application example of said invention.

Figure 4 is a development perspective view of yet another application example of said invention.

Reference numerals

(10)...synostosis device, (17)...electronic module housing,
(20)...electronic module, (90)...healing acceleration device,
(95)...brace, (102)...electronic module, (108)...mesh electrode
frame, (110)...bone graft, (112)...retainer.

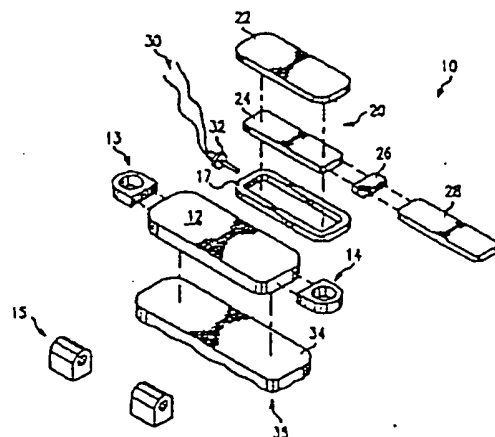


Figure 1

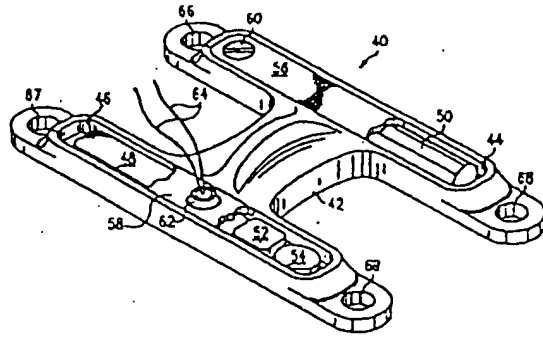


Figure 2

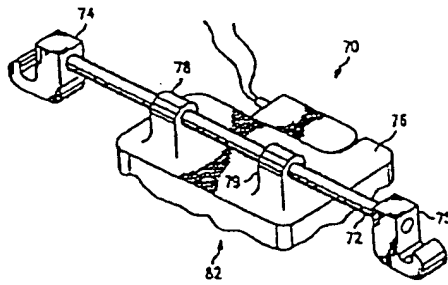


Figure 3

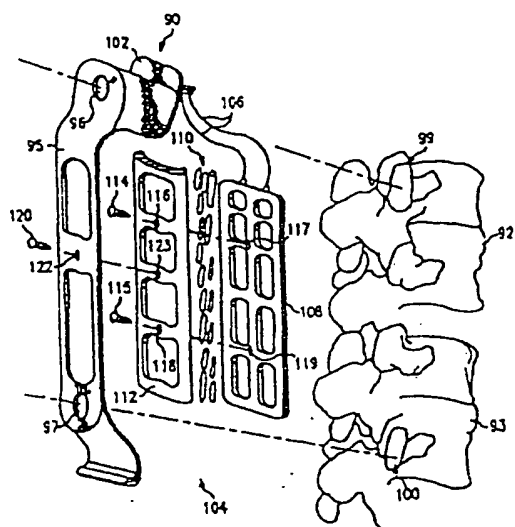


Figure 4